510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER	SurgiQuest, Inc. 12 Cascade Boulevard, Suite 2B Orange, CT 06477
CONTACT PERSON	Kourosh Azarbarzin Founder & C.E.O. - SurgiQuest, Inc.
DATE PREPARED	December 29, 2006
CLASSIFICATION	Laparoscopic trocar, GCJ Class: II
COMMON NAME	Disposable Endoscopic Optical Trocar & Cannula
PROPRIETARY NAME	SurgiQuest™ Elastomeric Optical Trocar & Cannula *(Trademark name to be determined)*
PREDICATE DEVICE	Surgiport™ Blunt Tip Trocar U.S. Surgical Corp. (Norwalk, CT) K903419 EndoPath III™ Trocar System Ethicon Endo-Surgery, Inc. (Cincinnati, OH) K032676
DEVICE DESCRIPTION	The subject is a surgical trocar and cannula composed of biosafe materials. The device incorporates an expandable elastomer sheath, which serves to hold the cannula vertically in place during endoscopic surgery. The device is used to create and maintain a port of entry during endoscopic surgery. It is fully disposable and is intended for single use only.
TESTING	The device has been tested to show its ability to adequately maintain its position within the abdominal wall during laparoscopic surgery. Also, bench top and animal testing has confirmed that insertion and removal forces are substantially equivalent to the predicate devices.

MAR 14 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SurgiQuest, Inc.
% Kourosh Azarbarzin
Founder & CEO
12 Cascade Boulevard, Suite 2B
Orange, Connecticut 06477

MAR 14 2007

Re: K063859
Trade/Device Name: SurgiQuest™ Elastomeric Optical Trocar & Cannula *(Trademark name to be determined)*
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 5, 2007
Received: March 5, 2007

Dear Kourosh Azarbarzin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT FOR INDICATIONS FOR USE

510(k) Number: _____

Device Name: SurgiQuest™ Elastomeric Optical Trocar & Cannula *(Trademark name to be determined)*

Indications for Use: The SurgiQuest™ Elastomeric Optical Trocar and Cannula has applications in abdominal and thoracic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

Prescription Use: Yes

DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K063859